

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

STATE OF IOWA *ex rel.*
THOMAS J. MILLER,
ATTORNEY GENERAL OF IOWA,

Plaintiff,

v.

OSMOSIS, LLC,
a Colorado corporation;

HARMONIZED WATER, LLC,
a Colorado corporation;

and

BENJAMIN TAYLOR JOHNSON, in his
individual capacity and corporate capacities;

Defendants.

EQUITY No. EQCE081282

PETITION IN EQUITY

The State of Iowa *ex rel.* Attorney General Thomas J. Miller, through Assistant Attorney General Steve St. Clair, states as follows in this enforcement proceeding against the above-named Defendants under the Iowa Consumer Fraud Act, Iowa Code § 714.16 (CFA) and the Older Iowans Law, Iowa Code § 714.16A:

INTRODUCTION

Benjamin Johnson is in the business of selling ordinary water at premium prices by claiming that he has treated the water in ways that imbue it with amazing medicinal or cosmetic properties. Johnson claims that ingesting his water can protect against cancer-causing UV rays, repel mosquitos that might carry the Zika virus, protect the body from pathogens, cure acne, reverse the aging process, and perform various other near-miraculous feats.

Johnson, who is referred to as *Dr. Johnson* in advertisements without disclosure of the fact that he was forced to surrender his Colorado license to practice medicine in 2001, claims that the almost magical properties of his water derive from using radio waves to “imprint” certain frequencies on the water, with different frequencies producing different beneficial effects. Johnson uses a machine called the Harmonizer to “imprint” the desired frequencies.¹

Although the imprinting of frequencies to transform ordinary water into a treatment or cure for a multiplicity of conditions is almost certainly pure bunk – pseudo-science at its worst – the Attorney General is not required to prove that the frequency-imprinting concept is as pseudo-scientific as it appears. That is because Iowa law requires those who make performance claims for a product to be able to substantiate those claims. This lawsuit alleges that dramatic claims for various “harmonized” water products cannot be substantiated, that faulty testimonials and other deceptive and unfair practices have infected much of the marketing in question, and that Johnson and his companies inexcusably put consumers, young and old, at risk of wasting their money and, in many instances, endangering their health.

Plaintiff respectfully submits that, on these facts, the Court should impose upon Defendants the full range of remedies available under the Consumer Fraud Act and the Older Iowans Law, including restitution to victims, injunctive relief, and civil penalties of \$40,000.00 per violation per defendant, increased to \$45,000.00 for each violation committed against older Iowans.

PARTIES AND VENUE

1. Thomas J. Miller is the Attorney General of the State of Iowa, and is expressly authorized by Iowa Code § 714.16 (7) of the Consumer Fraud Act to bring this action on behalf of the State of Iowa.

¹ As it happens, the Harmonizer device was created by Iowan Vernus Schroeder in his Carroll, Iowa workshop. Schroeder sold a Harmonizer to Osmosis in 2009.

2. Osmosis, LLC (“Osmosis”), a for-profit, limited liability company, was incorporated in Colorado in 2006, and has a business address of 30746 Bryant Drive, # 410, Evergreen, Colorado. According to Osmosis and its CEO, Defendant Johnson, Osmosis is owned by Johnson (74.25%), its president Robin McGee (3.5%), its COO Aaron Burke (1.5%), and its vice-president of sales, Krista Davis (.75%). In addition, Tom Malley owns 20%.

3. Harmonized Water, LLC (“Harmonized Water”), a for-profit, limited liability company, was incorporated in Colorado in 2009 and has the same business address as Osmosis (above). Since its inception, Harmonized Water has had only one employee, Mr. Johnson, who has also served as the company’s sole officer and director. According to Osmosis and Johnson, the company is owned by Johnson (90.5%), Robin McGee (2%), Char Fontanills (2.5%), and Tom Malley (5%).

4. Benjamin Taylor Johnson, a resident of Evergreen, Colorado, is CEO and primary owner of Osmosis, and the sole officer and primary owner of Harmonized Water. Upon information and belief, Mr. Johnson exercises a degree of involvement in, and control over, the activities of the corporate defendants sufficient to make him responsible under the Consumer Fraud Act for the violations alleged herein.

5. Venue is proper in Polk County pursuant to Iowa Code § 714.16 (10) because Defendants have directed deceptive solicitations regarding various of the products at issue, and have sold such products, to residents of Polk County.

KEY LEGAL PROVISIONS

6. Iowa Code § 714.16 (2)(a) of the Consumer Fraud Act (“CFA”) provides, in pertinent part:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a

person has in fact been misled, deceived, or damaged, is an unlawful practice.

It is deceptive advertising within the meaning of this section for a person to represent in connection with the lease, sale, or advertisement of any merchandise that the advertised merchandise has certain performance characteristics, accessories, uses, or benefits or that certain services are performed on behalf of clients or customers of that person if, at the time of the representation, no reasonable basis for the claim existed. The burden is on the person making the representation to demonstrate that a reasonable basis for the claim existed.

7. Iowa Code § 714.16 (1) of the CFA provides the following definitions (among others):

(a) The term "advertisement" includes the attempt by publication, dissemination, solicitation, or circulation to induce directly or indirectly any person to enter into any obligation or acquire any title or interest in any merchandise.

(f) "Deception" means an act or practice which has the tendency or capacity to mislead a substantial number of consumers as to a material fact or facts.

(i) The term "merchandise" includes any objects, wares, goods, commodities, intangibles, securities, bonds, debentures, stocks, real estate or services.

(n) "Unfair practice" means an act or practice which causes substantial, unavoidable injury to consumers that is not outweighed by any consumer or competitive benefits which the practice produces.

8. In further describing what the attorney general must allege and prove under the CFA, Iowa Code § 714.16 (7) provides, in pertinent part:

Except in an action for the concealment, suppression, or omission of a material fact with intent that others rely upon it, it is not necessary in an action for reimbursement or an injunction, to allege or prove reliance, damages, intent to deceive, or that the person who engaged in an unlawful act had knowledge of the falsity of the claim or ignorance of the truth.

9. In describing remedies under the CFA, Iowa Code § 714.16 (7) provides, in pertinent part, as follows:

If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by

this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys...which have been acquired by means of a practice declared to be unlawful by this section

In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person. . . .

10. Subsections 714.16A (1)(a) & (3) of the Older Iowans Law provide, respectively:

If a person violates section 714.16, and the violation is committed against an older person, in an action by the attorney general, in addition to any other civil penalty, the court may impose an additional civil penalty not to exceed five thousand dollars for each such violation.

As used in this section, 'older person' means a person who is sixty-five years or age or older.

Factors to be considered in imposing an additional civil penalty under section 714.16A are set forth at Iowa Code § 714.16A (2).

ADDITIONAL FACTUAL BACKGROUND

11. Although upon information and belief the marketing of many of Defendants' products has involved violations of the Consumer Fraud Act – particularly the Harmonized H₂O products – this Petition will highlight two products in particular, namely UV Neutralizer and Harmonized H₂O Mosquito, each of which gives rise to acute public safety concerns. In each instance, Defendants recklessly gave consumers hollow assurances that they were protected from known health hazards. UV Neutralizer has been sold to Iowans since at least as early as 2013 through local businesses that offered Osmosis products, and, upon information and belief,

Harmonized H₂O Mosquito and numerous other Osmosis products have been marketed to Iowa residents during the same period through such local retailers.

UV Neutralizer

12. In 2012, Osmosis began selling UV Neutralizer, advertised as an ingestible liquid that would protect against the damaging rays of the sun.² The product was created, it was claimed, by using a machine called the Harmonizer to imprint frequencies upon ordinary water. The product worked, it was claimed, by generating scalar waves that vibrated above the skin, cancelling the potentially injurious effects of solar radiation. A few pumps from the spray dispenser into one's mouth, it was claimed, afforded three hours of protection from the sun comparable to what an SPF 30 sunscreen would provide.

13. Osmosis provided a bottle of UV Neutralizer to the Attorney General's Office in November of 2016. The 3.4 fluid ounce spray bottle, which was recently offered for \$30 on Osmosis's website, contained the following on its label:³

- a) An ingredients statement that listed only water, but an additional statement that the contents were "enhanced with proprietary frequencies in the form of scalar waves."
- b) A "suggested use" section that recommended taking "5 pumps" one hour before going outside (7 pumps if you weigh more than 175 pounds), and then, after monitoring sun exposure carefully, taking a second round of pumps after three hours in the sun.

14. Attached to this UV Neutralizer bottle was a "hang tag" containing additional information. The hang tag prominently stated that the product "Neutralizes UV Radiation" and "Allows for increased sun exposure (30x more than normal)." The hang tag also recommended an initial test, applying sunscreen elsewhere but leaving an arm exposed during time in the sun:

² The product was originally called UV Protection, but the name was changed in about June of 2014.

³ Images of a UV Neutralizer container, accompanied by a more readable transcription of the contents of the back label, are appended as Attachment I. Although these are images of the "tan enhancer" version of the product, the bottle of the "no tan" version is substantially the same.

“If the arm does not burn, then you know it will work for you.” A copy of the hang tag is appended as Attachment II.

15. The importance of effective protection from the sun’s rays is well-established.⁴ Skin cancer (basal cell carcinoma, squamous cell carcinoma, and melanoma) is the most common of all cancers in the United States. The vast majority of skin cancers are caused by exposure to UV radiation from the sun. One in five Americans will develop skin cancer in the course of a lifetime. More than 3.5 million skin cancers, afflicting more than 2 million U.S. residents, are diagnosed each year. Melanoma is the deadliest form of skin cancer, accounting for the vast majority of skin cancer deaths. It is projected that in 2017 about 87,000 new cases of invasive melanoma will be diagnosed in the U.S., and that almost 10,000 Americans will die of melanoma. About 92 Iowans die of melanoma each year. An estimated 86% of melanomas can be attributed to UV exposure from the sun. A person’s risk for melanoma doubles if he or she has had more than five sunburns. In addition, UV exposure can harm the immune system and cause premature skin aging.

16. UV exposure can be particularly harmful in childhood. Melanoma accounts for up to 3% of pediatric cancers. In addition, sun damage is cumulative; about one-quarter of lifetime sun exposure occurs during childhood. Suffering one or more blistering sunburns in childhood or adolescence more than doubles a person’s chances of developing melanoma, the most lethal skin cancer, later in life.⁵

⁴ See National Institute of Health’s <https://www.cancer.gov/types/skin/hp/skin-prevention-pdq>; American Cancer Society’s <https://www.cancer.org/cancer/skin-cancer.html>; Centers for Disease Control and Prevention’s www.cdc.gov/cancer/skin; Skin Cancer Foundation’s www.skincancer.org/skin-cancer-information/skin-cancer-facts

⁵ See esp. www.cdc.gov/cancer/skin; www.skincancer.org/skin-cancer-information/skin-cancer-facts

17. Despite the clear dangers to the public, Defendants “launched” this product in 2012 without any valid testing to ensure it really provided the protection claimed. As Defendant Johnson stated in March of 2014: “We have been selling it for two years with rave reviews but clinicals have not been done.”⁶ In effect, Defendants used the public – adults and children alike – as guinea pigs, even though the stakes involved cancer. In fact, no clinical testing on the efficacy of the product was performed until a test in mid-2014 and a second test in 2016, and, as discussed in detail below, those tests were seriously flawed.⁷

Specific advertising claims for UV Neutralizer

18. Defendants have aggressively promoted UV Neutralizer, through company websites, online videos, news releases, media interviews, and otherwise. Examples of promotional claims include the following:

- a) “Harmonized H₂O has discovered a way to cancel out UVA and UVB radiation before it hits your skin!” (Osmosis news release)
- b) Osmosis’s website refers to UV Neutralizer as the “world’s first drinkable sunscreen,” and boasts that it had gone viral, “attracting record media coverage.”
- c) “Physician endorsed, no chemicals, non-toxic, this is simply purified water imprinted with unique, vibrational waves which isolate out the precise frequencies needed to protect you from UV rays. The frequencies that have been imprinted on water will vibrate on your skin in such a way as to cancel approximately **97%** of the UVA and UVB rays (similar to broad spectrum SPF 30 products).” (Osmosis news release; emphasis in original)
- d) “Finally, sun protection without the greasy, controversial, melanoma promoting sunscreens that lasts for three hours and allows for Vitamin D formation, is waterproof ... all from ½ a teaspoon of harmonized water.” (Osmosis news release)
- e) “[E]xplains Dr. Johnson, ‘thousands of people across the country are using it right now to avoid getting a sunburn.’” (Osmosis news release)

⁶ The accuracy of Johnson’s “rave reviews” claim is suspect at best. Johnson stated in 2016 that “We do not save complaints. There have been very few over the last several years and they are typically via a phone call.”

⁷ The 2014 study will be referred to as the Ver Hoeve study, for Paul Ver Hoeve, who is listed as lead author of the study report, and the 2016 study will be referred to as the IRSI study, for the company that conducted the testing, International Research Services, Inc.

- f) “Approximately 98% of people will be protected by this technology. The healthier the immune system, the longer their skin can stay in the sun. For example, kids often can stay outside for 6+ hours with repeated doses because their immune system is very strong.” (Osmosis’s “Guide” to UV Protection)
- g) In response to a March 2014 question from *Cosmopolitan* magazine about whether there is any need to “use additional SPF” along with the UV Neutralizer, Osmosis conveyed Johnson’s response: “You do not need any other coverage.”
- h) A May 2016 article in *InStyle* magazine (“Behold: Drinkable SPF Really Exists”) cites Johnson as the source for the representation that UV Neutralizer “protects overlooked areas like your eyes and scalp.”
- i) Johnson’s May 2016 statement for use in an online article on drinkable sunscreens: “Osmosis’ UV Neutralizer is the best solution for sun protection in most situations! It does not rinse off in water and you do not need to rub greasy creams all over your body. It neutralizes UVA/UVB/UVC/Infrared radiation prior to contact with the skin. Most chemical sunscreens actually double inflammation in the skin. UV Neutralizer is safe”

Lack of substantiation for efficacy of UV Neutralizer

19. Defendants’ various promotional claims and other advertisements for UV Neutralizer have included the following representations (among others) about the product’s performance for which a reasonable basis was required at the time the representations were made:

- a) UV Neutralizer “utilize[es] frequencies that work against the damaging effects of the sun.”
- b) UV Neutralizer “[n]eutralizes UV radiation.”
- c) UV Neutralizer allows for “30x more” sun exposure.

20. Through a Civil Investigative Demand (CID)⁸ in August of 2016, the Attorney General asked Defendants Osmosis and Johnson to provide the substantiation required by Iowa law for each of the above three claims. On November 15, 2016, they responded:

⁸ A Civil Investigative Demand is an information-gathering tool authorized by subsections (3) and (4) of the Consumer Fraud Act. It is comparable to an investigative subpoena. *See State ex rel. Miller v. Smokers Warehouse Corp*, 737 N.W.2d 107, 109–10 (Iowa 2007).

Similar to how sound cancellation works, we imprint frequencies onto water molecules that can cancel UVA/UVB/UVC/Infrared. This is substantiated by the years of success and two clinical trials.⁹

21. The CID also asked Osmosis and Johnson to provide the basis for the advertised claim that the “scalar waves” contained in UV Neutralizer “vibrate above the skin to neutralize UVA and UVB, creating protection comparable to an SPF 30.” Defendants responded:

We cannot prove the actual existence of scalar waves above the skin. However, the clinical trials prove that our theory is correct.

Clinical trials of UV Neutralizer

22. Defendants rely heavily on two clinical trials as substantiation for their efficacy claims for UV Neutralizer, and also as support for their representations that it is the vibration of scalar waves above the skin that delivers the UV protection. That reliance is misplaced.

23. At the outset, it is important to note that a reasonable basis for Defendants’ efficacy and other performance claims must exist *at the time the claims are made*. Iowa Code § 714.16 (2)(a). The claims in question were made at least as early as 2012, and have been made continuously since then. However, the two clinical trials were conducted in 2014 (the Ver Hoeve study) and in 2016 (the IRSI study) – well *after* Defendants began making their claims.

24. In any event, even if these clinical trials had been conducted before UV Neutralizer sales began in 2012, they do not provide the level of substantiation required by law.

The 2014 Ver Hoeve Clinical Trial

25. In about July of 2014, Osmosis issued a news release announcing that UV Neutralizer, touted as “the world’s first drinkable sunscreen,” had just undergone a randomized clinical trial, with “definitive” results that “prove that the scalar wave technology in Harmonized Water works.” As noted above, Osmosis points to this clinical trial as one of the

⁹ The clinical trials in question are discussed in detail below.

two studies providing scientific support for the various claims made for the effectiveness of UV Neutralizer. The final report of this clinical trial, titled “Evaluation of a Novel Form of Sun Protection,” is appended as Attachment III, and will be referred to simply as “the Report” in the remainder of this section.

26. The clinical trial described in the Report involved the following serious defects (among others):

a) The Report identifies the lead author as “Paul Ver Hoeve, MD, FACS” (as does the Osmosis news release quoted above). “FACS” stands for Fellow of the American College of Surgeons. However, Ver Hoeve has acknowledged that he has never been a Fellow of the American College of Surgeons, and recently stated that “the association of my name with the title ‘FACS’ should not have been made by whomever it was that put [the Report] together.”

b) Although Osmosis has called this clinical trial “independent,” Osmosis proposed the study to Ver Hoeve, an acknowledged “client” of Osmosis; sent Osmosis Marketing Manager, Katy Hebert,¹⁰ to be present while the study was conducted; compensated the study subjects (\$200 each); and played an active role in performing a final review of the results. In addition, Johnson is listed as co-author of the Report.¹¹

c) Ver Hoeve was financially interested in the result. Ver Hoeve received \$5,000 in Osmosis products as compensation for his role in conducting this clinical trial, products evidently sold through the clinic he owns.

d) Ver Hoeve’s disciplinary history made him a questionable choice to conduct an important clinical trial with strong public health implications. Ver Hoeve was disciplined by the Medical Board of California, effective January 2, 2003, for having been convicted in 2000 of mail fraud (a felony) in connection with charges that he had defrauded Medicare by billing for supervised cardiograms but providing unsupervised cardiograms; he was suspended by the Board from the practice of medicine for 90 days, and placed on probation for five years.

e) Although Osmosis has claimed that this clinical trial was “peer reviewed,” it was not. Peer review is an aspect of the publication of certain scientific articles, and the Report was evidently not published, and was not peer reviewed.

¹⁰ Ms. Hebert’s precise role in this study is currently unknown, but her own personal experience with UV Neutralizer was indicated in a March 31, 2014 email, in which she wrote “I didn’t do well on it,” attributing the lack of effectiveness to issues that made her a “special case.”

¹¹ In fact, Johnson may have been the sole author, despite the fact that the Report reads as if it is Ver Hoeve’s first person account. Ver Hoeve recently insisted that he did not author the Report.

f) The test subjects were given 2-3 ml. of UV Neutralizer (the Report's abstract states that each subject ingested 3 ml. but the introduction is less precise, indicating 2-3 ml.). Either way, the dose tested was higher than the 2 ml. "serving size" stated on the product container. Setting aside the likelihood that the tested substance was plain water, in which case the number of pumps would make no difference, it is fundamental that a test to establish efficacy must use the same dosage as consumers are instructed to take. (*see* Attachment I).

g) The trial involved a small sample size of 24 subjects. Although the Report states that all of the subjects were patients of Dr. Ver Hoeve – which would itself be problematic, given likely patient loyalties – in fact the pool of subjects was a mix of Ver Hoeve's "clients," friends of his clients, and Ver Hoeve's family members (wife and son).

h) Although the Report claims that the 24 test subjects were "randomly selected," Ver Hoeve has acknowledged that there was no particular process for selecting participants.

i) In addition to sample size and randomness issues, the clinical trial lacked basic elements of proper scientific testing. There was no control group, so there was no blinding whatsoever; all subjects and all testers were aware that only the UV Neutralizer was being administered, with no placebos. UV light was applied to subjects in an uncontrolled and uncalibrated manner; the Report states only that subjects were "exposed to one hour of sun to one side of the body between noon and 1pm on June 28, 2014 in San Diego." In addition, the assessment of how well the product worked was made by Dr. Ver Hoeve, based on his own visual inspections.¹²

j) Documents related to the clinical trial were not retained: Osmosis has stated that it "did not see a need to keep the notes after the final results were calculated."

27. Even setting aside the flaws in the design and conduct of the clinical trial, the results of the trial provide dubious support for the efficacy claims made for UV Neutralizer. Of the 24 subjects, five subjects suffered "minor or partial sunburns," and another three "had significant sunburns." Thus, fully one-third of the test subjects were burned to some degree, some "significantly."¹³ Despite these burns, the Report characterizes the results as "definitive." Similarly, an Osmosis news release announcing the clinical trial results described the test as an

¹² The extent to which Marketing Director Hebert or other Osmosis representatives may have participated in making the evaluations is currently unknown.

¹³ Even the group of subjects classified as 'no burn' included some dubious 'successes.' One admitted that she "felt sunburnt" despite a lack of redness, and another admitted that "some redness showed up, but not too bad."

“overwhelming success.”

28. An “after” photo array of the sixteen subjects who are claimed to have demonstrated the product’s efficacy (excluding the eight who were burned) has been posted on Osmosis’s website.¹⁴ To explain why the skin of some subjects appeared to have a reddish tone, the posting stated: “Please also note that some participants did indeed have skin color from previous sun exposure when they attended the event.” This claim – that some subjects had sun-reddened skin before the trial began – is inconsistent with the “requirement” communicated to study participants that “your skin cannot be sun burned at the time of the test.” In any event, Osmosis representatives recognized this perceptible redness as a problem at the time. Shortly after the testing, Osmosis’s publicist emailed the company regarding her concerns: “[S]ome of the pictures that are classified as no burn look like the patient has reddish skin. This can be bad if people decide to use this against us.”

29. The purported authors of the Report observe that in general “[t]he incidence of skin cancer has risen dramatically”; acknowledge that “the product is water (there is no other active ingredient)”; admit to being “skeptical” of the claims that scalar waves “vibrate above the skin to neutralize UVA and UVB”; acknowledge that “there has never been substantial evidence that these waves can be imprinted on water”; and observe that “there does not appear to be a test to prove the deposition of scalar waves into the water.” Nevertheless, 24 patients were asked to expose one side of their bodies to the midday, Southern California sun, continuously for an hour, with no protection from the sun other than the 2 to 3 ml. of water they sprayed into their mouths beforehand. The Report does not indicate that there had been any effort to seek Institutional Review Board participation to ensure that participants were not subjected to

¹⁴ http://www.osmosisskincare.com/Assets/Files/UV_Neutralizer_Clinical_Study_Photos-140730.pdf

unreasonable risk of harm.¹⁵

30. This clinical trial does not itself provide a reasonable basis for the efficacy claims Defendants have made for UV Neutralizer. Neither does it make any significant contribution to establishing a reasonable basis.

The 2016 clinical trial by International Research Services, Inc.

31. In 2016, Osmosis arranged for a second clinical trial, this time to be conducted by International Research Services Inc. (“IRSI”) of Port Chester, New York. A final report of the study, entitled “A Two-Day Randomized, Controlled, Crossover Clinical Study to Evaluate the Efficacy of One Product on Skin Condition After UVA/B Exposure,” concluded that the subjects who received UV Neutralizer showed “a superior tanning effect” and “less erythema”¹⁶ than the placebo group: “[U]se of the Active product affected [sic] more statistically significant improvements in skin color compared to placebo.”

32. Defendants’ reliance on this clinical trial as key support for its efficacy-related claims is misplaced for the following reasons (among others):

- a) All test subjects were given “7 pumps” of UV Neutralizer. That dose is 40% higher than the “5 pumps” the product container prescribes for anyone weighing 175 lbs. or less, and most study participants did weigh less than 175 lbs. So the dose tested was, for most subjects, higher than the dose prescribed on the product label.
- b) IRSI had a financial incentive to keep doing efficacy studies for Osmosis, creating pressure to deliver positive results. IRSI completed an efficacy study for Osmosis in October 2015 on “Catalyst AC-11,” the company’s “DNA repair” and “age reversing serum,” as part of a regimen of topical Osmosis products purporting to tighten skin and

¹⁵ Institutional Review Boards review clinical investigations pursuant to regulations issued by the FDA, as part of a framework designed to protect the rights and welfare of the human subjects. Paradoxically, the Report does cite ethical concerns, but only in support of the decision not to do double-blind testing: “The decision was made not to do a double-blind test ... because of the ethical implications of knowingly causing a sunburn in many people.” (Att. III) Given the acknowledged lack of evidence for scalar waves as a UV-protective mechanism, this testing appears to have recklessly, if not knowingly, caused a sunburn in several test subjects.

¹⁶ IRSI has referred to erythema as “redness,” and an online medical reference refers to it as “redness of the skin that results from capillary congestion. Erythema can occur with inflammation, as in sunburn.” <http://www.medicinenet.com/script/main/art.asp?articlekey=3306>

improve the appearance of lines and wrinkles; the study produced positive results, finding that Osmosis's regimen significantly improved skin appearance. IRSI completed another efficacy study for Osmosis in April of 2016 on "Skin Perfection," the company's ingestible Harmonized Water treatment for acne; the study produced positive results, finding that the water was an effective acne treatment.¹⁷ Upon information and belief, each IRSI study involved a substantial payment by Osmosis.¹⁸

c) The UV Neutralizer study itself appeared to involve communications between IRSI and Osmosis that were inconsistent with rigorous application of scientific principles. In a September 2016 email exchange, principal IRSI investigator Robert J. Frumento indicated that he was in the process of finishing the tanning data by putting the data into tables, and he made this request of his Osmosis contact: "[C]an you unblind it for me to put in the tables." His Osmosis contact proceeded to tell him that "Product A is the Active UV Neutralizer" and that "Product B is the placebo."

d) The UV Neutralizer study involved confusion regarding which cohort received the placebo, and whether there was any way to confirm which of the two waters administered to test subjects was the Harmonized Water (UV Neutralizer), and which was ordinary water (the placebo). On October 19, 2016, an Osmosis consultant monitoring the study emailed Frumento, evidently concerned about initial study results that showed better performance by the plain water: "[T]he active was product A ... not B ... and the statistical significance in the study seems to be for Product B ... was there a mix up ...?" Frumento replied that he wanted to test the actual product handed out to groups A and B, to confirm which was the active, and which the placebo: "[C]an I run some kind of test to confirm correct labelling?" The Osmosis consultant responded that there was no test she knew of to distinguish active from placebo, and speculated that the staff member involved in tabulations may have "switched/inverted the data." The Attorney General does not currently know how this was resolved, but the study results that emerged supported the efficacy of UV Neutralizer.

e) Testing irregularities may be of particular concern given the apparent professional history of Robert J. Frumento, the principal investigator on each of the three clinical studies IRSI is known to have conducted for Osmosis. A "Robert J. Frumento" – upon information and belief, the same person – was cited for research misconduct in connection with the withdrawal by Columbia University of an article entitled *Dexmedetomidine infusion is associated with enhanced renal function after thoracic surgery*, which listed "Robert J. Frumento, MS, MPH" as lead author. The article had been published in the *Journal of Clinical Anesthesia* in September 2006. Columbia

¹⁷ As a possible indication that IRSI was motivated to conduct the testing in a manner that ensured retaining Osmosis as a customer, IRSI's acne study evidently began as a "Double-Blind, Randomized, Placebo-Controlled Clinical Study," but later underwent a remarkable re-design, namely, "removal of the placebo group."

¹⁸ At the very same time lead IRSI investigator Frumento was finishing the UV Neutralizer data, he was writing a proposal for testing Osmosis's new eyelash growth formula, at the request of an Osmosis representative. In a similar vein, Frumento was asked by an Osmosis consultant in April 2016 about additional testing relating to the UV study, adding "it could pave the way for another study."

University's August/September 2013 retraction statement read, in pertinent part:

*The University completed an investigation into allegations of research misconduct against Mr. Robert Frumento, who was previously employed as a Research Coordinator by the Department of Anesthesiology. The University has concluded that there was evidence of falsification and fabrication by Mr. Frumento, who had primary responsibility for collecting and analyzing the data for this paper. The findings include numerous discrepancies between the source material and the reported data, which provided false support for reportedly significant results. The University concluded that these findings constitute research misconduct by Mr. Frumento. In addition, the University found that some of the credentials claimed by Mr. Frumento were not accurate. . . . The University found that Mr. Frumento had not received a Master of Science degree from any institution.*¹⁹

(f) When later confronted by the Attorney General with Osmosis's reliance on the IRSI study to support the efficacy claims for UV Neutralizer, the President of IRSI asserted that the testing "has absolutely nothing to do with sun protection or 'sunscreen,' and that "primary focus of the IRSI study was to evaluate the product as a 'tanning accelerator (stimulate the production of melanin in the cells]' not in any way as a sun protectant."

33. This clinical trial does not itself provide a reasonable basis for the efficacy claims Defendants have made for UV Neutralizer. Neither does it make any significant contribution to establishing a reasonable basis.

Testimonials for UV Neutralizer

34. Defendants' harmonized water website has promoted UV Neutralizer through the following consumer testimonials (among others) as recently as March of 2017:

a) *"Determined to put this water to the test I drank a cap full 1-hour before venturing out. . . . I never experienced the sting and bite from the sun that I would normally feel . . . but to my delight a slight tan did exist. Harmonized water is like a second skin of protection, which is healthy and natural. I love it!"* Attributed to "Kay, New Zealand."

"Harmonized UV Water is a fantastic answer to sun protection living in New Zealand. Kiwi's are under constant attack from harsh sun because of the depleted O-Zone layer affecting New Zealand."

¹⁹ See [http://www.jcafulltextonline.com/article/S0952-8180\(06\)00136-X/abstract](http://www.jcafulltextonline.com/article/S0952-8180(06)00136-X/abstract)

The website did not disclose: that “Kay” was an Osmosis representative;²⁰ that no effort had been made to verify the accuracy of the statements; that the testimonials were not current or even recent, dating from July of 2011; or that Osmosis quit selling UV Neutralizer in New Zealand after that country’s Advertising Standards Authority declared in July of 2014 that Osmosis’s online advertising for the product was “misleading, abused the trust and exploited the knowledge of the consumer by stating the product offered sun protection using scientific terminology without adequate substantiation.”

- b) *“I was thrilled to hear about the UV water and tested it on my son who had a sport camp every day for a week. The temperature that week was ranging from 98 to 102 degrees. When he came home . . . his skin was neither red nor burnt. My son told me: ‘the water really works!’ No need to apply sunscreen.”* Attributed to “Caroline.”

The website did not disclose this person’s status as a skin care representative with links to Osmosis; or that no effort had been made to verify the accuracy of this 2011 testimonial statement.

- c) *“I tested the UV Protection Harmonized Water (my skin burns in 15 minutes w/o sunscreen and so I was nervous) SUCCESS!! I was outside for 2 hours with NO sunscreen during peak hours and wasn’t even pink! My year and a half year old drinks it as well and hasn’t burned once this summer and is outside every day! Thank You, Thank You for this product!”* Attribution: “via Facebook.”

When the Attorney General sought information from Defendants regarding this testimonial, Defendants’ November 2016 response indicated that the testimonial was posted to the company’s Facebook page in about August of 2011, but that no effort had ever been made to verify its accuracy. Defendants further indicated that they were unable to identify the source of the testimonial. Despite these issues, this testimonial continued to appear on the osmosisskincare.com website as recently as early 2017.

- d) *UV Neutralizer “is useable for just about everyone.”* Attributed to “Danielle”

Danielle’s video testimonial appears on an Osmosis webpage touting the results of the Ver Hoeve study. Assuming that this is the same ‘Danielle’ who participated in the Ver Hoeve study, Osmosis used the testimonial above despite the fact that she was one of the eight subjects with acknowledged sunburns; her study questionnaire included the notation, “burned on chest.”

- e) *“I didn’t burn at all.”* Attributed to “Anne”

This video testimonial also appears on the Osmosis webpage relating to the Ver Hoeve study. It fails to disclose that the testimonial giver’s full name is Anne Ver Hoeve, and that she is the wife of the lead investigator, Paul Ver Hoeve.

²⁰ Various other testimonial providers were also in the cosmetic/aesthetician business, but it is not yet known whether they too sold Osmosis products.

35. In addition to the deceptions and omissions noted above, upon information and belief: such testimonials are misleading, in that they do not represent the experience that most users can expect to have; they have not been adequately verified; and they are otherwise in violation of the CFA.

Lack of substantiation for efficacy of Harmonized H₂O Mosquito

36. Since at least as early as August of 2014, Defendants have marketed, to Iowans and others, an ingestible mosquito repellent called Harmonized H₂O Mosquito, which is priced on the Osmosis website at \$30 for a small bottle (3.38 fluid ounces).

37. Defendants have made the following performance claims (among others) regarding Harmonized H₂O Mosquito:

- a) “Mosquito deterrent [--] This formula contains the Osmosis Harmonized Water enhanced with proprietary frequencies in the form of scalar waves.” (*Appears on the container.*)
- b) The product fends off mosquitos by “using frequencies that mosquitos find annoying! One hour after ingesting, these frequencies will be vibrating at the skin level and will deter mosquitos from landing on you. While the reports suggest that this is nearly 100% effective, you can expect the occasional kamikaze mosquito to irregularly break through. . . . [The product] creates a vibrating shield from head to toe without any chemicals.” (*Has appeared on osmosisskincare.com website.*)

38. Upon information and belief, Defendants cannot provide the level of substantiation required by law for their claims of efficacy for Harmonized H₂O Mosquito.

Testimonials for Harmonized H₂O Mosquito

39. Defendants have presented the following “reviews” of Harmonized H₂O Mosquito on their website:

- a) After drinking the water, “I have not had a run in with them [mosquitos] while walking my dog as well as standing around areas where everyone else scrambles to get inside to get respite from bites.” (Attributed to Silvia Flavin, 7/18/16.)
- b) “Best mosquito repellent! I call this the miracle water! . . . This water has truly been life changing. I’ve . . . been using this water every day for 26 days and not one

single bite. I stopped using it the last 2 nights and woke up to 5 bites from the neck down.” (Attributed to Vanessa, 8/31/14.)

c) “I went wake boarding at a lake north of Denver and took the Mosquito water and did not get bit the whole time I was out on the lake.” (Attributed to Frank Duran, undated.)

40. Upon information and belief, such testimonials are misleading, in that they do not represent the experience that most users can expect to have; they have not been adequately verified; and they are otherwise in violation of the CFA.

The consequences of promoting an ineffective mosquito repellent

41. The marketing of an ineffective shield against mosquito bites can have serious consequences. Mosquito borne diseases include West Nile virus, malaria, and the Zika virus.²¹

42. Despite the potentially dire health consequences of mosquito bites, Defendants have seen public concerns with the Zika virus in the southeastern U.S. as an opportunity to promote Harmonized H₂O Mosquito. Osmosis President Robin McGee emailed the company’s publicist about the product in August 2016, asking for help to “position it as a holistic mosquito repellent . . . and to create awareness with it especially as it pertains to the Zika virus.” The publicist demurred; concerned about “what it [Zika] is doing to newborns,” the publicist counseled against appearing to capitalize on the issue, “especially if there might not be any studies done yet.” The publicist’s reluctance prompted Defendant Johnson to weigh in:

*We are not trying to scare anyone. We offer a holistic mosquito repellent and there have been several news stories talking about **all the repellent being sold** and what the options are. **They need to know about us.** The fact that we may have a treatment for Zika will not be included in this round :)*

Emphasis added.

²¹ While malaria and the Zika virus may not currently infect mosquitos in Iowa, Iowans often travel to areas that have infected mosquitos, both in the southern U.S. and worldwide.

Other Harmonized Water products

43. Like UV Neutralizer and Harmonized H₂O Mosquito, numerous other products sold by Defendants to Iowans appear to have only one ingredient: water. Defendants contend, however, that the water in each of these different products was infused with radio waves of a particular frequency selected to imbue that product with the desired cosmetic or medicinal properties. Based on a review of product information on Osmosis's website, the following Osmosis products appear to have water as the sole ingredient:

Skincare Products

Clear, a facial mask promoting healthy skin, stabilizing bacteria levels (\$26.00 for 100 ml.)²²

Wellness Products

Hangover, for relief of hangovers (\$30.00 for 100 ml.)

Skin Perfection, clears and detoxifies, treats rosacea, eczema, psoriasis (\$40.00 for 100 ml.)

Sugar Detox, addresses all aspects of sugar and sweetener overload (\$30.00 for 100 ml.)

Cramp-Free, alleviates menstrual discomfort (\$30.00 for 100 ml.)

Energize Me, provides an energy boost (\$30.00 for 100 ml.)

Digestive Health, alleviates digestive tract discomfort and bloating (\$30.00 for 100 ml.)

Hormone Health, addresses range of hormone-influenced conditions, including infertility, hair loss, libido, menopause, thyroid deficiencies (\$40.00 for 100 ml.)

Environmental Protection, promotes the release of environmental toxins (\$30.00 for 100 ml.)

Inner Harmony, balances cellular frequency to benefit multiple bodily systems (\$40.00 for 100 ml.)

Relax, reduces stress and promotes sound sleep (\$30.00 for 100 ml.)

²² The prices were derived from the website www.osmosisskincare.com on or about January 25, 2017. For comparison purposes, 100 ml. equals about 3.4 fluid ounces, or about 7 tablespoons.

Altitude, addresses altitude sensitivity and improves oxygenation (\$30.00 for 100 ml.)

Disruptor, cancels negative effects of pathogens, toxins, and bad memories (\$24.00 for 460 ml.)

Body Talk, counters negative effects of fear, anger, and sadness (\$30.00 for 100 ml.)

Vigor, improves testosterone activity, reduces hair loss, increases libido (\$40.00 for 100 ml.)

Joint Health, improves joint health and addresses many painful conditions (\$30.00 for 100 ml.)

Mini Harmonized H₂O kit, contains Digestive Health, Relax, Energize Me, Hangover Helper (\$16.00 for four 20 ml. items)

MD SkinCare Products

MD Clear, a spray with scalar waves promoting healthy skin, stabilizing bacteria levels.

44. Upon information and belief, Defendants cannot provide legally adequate substantiation for efficacy claims associated with its Harmonized Water products, and such products have been and are being marketed in a manner that is deceptive and unfair and otherwise in violation of the CFA.

Failing to disclose material facts regarding Johnson's status as a doctor

45. Defendants' advertising for Harmonized Water products (as well as for other Osmosis products) has emphasized Defendant Johnson's status as a doctor.

46. However, in a 2001 disciplinary proceeding before the Colorado State Board of Medical Examiners, Johnson was required to surrender his license to practice medicine after acknowledging: (a) that his staff had inflicted "extreme pain" on a patient in performing a laser hair removal procedure that Johnson had advertised as "virtually painless";²³ and (b) that Johnson

²³ The pain, related to facial burns, was intense and sustained enough to require prescription medication for its control. In addition, Johnson had promised the patient permanent hair removal backed by a two-year guarantee, but when the injured patient's hair reappeared the two-year guarantee "was not honored." Notably, Johnson had tried to withdraw his advertised guarantee "based upon his assertion that he had been misled as to the laser hair removal machine's

had performed a different laser procedure on the face of another patient, but “did not perform the procedure in a sterile fashion,” resulting in pain and hospitalization for a strep infection.²⁴

47. Although the Board’s 2001 order permitted Johnson to reapply for a license to practice medicine after the passage of at least ninety days, a late 2016 search of the Colorado Medical Board’s website indicated that Johnson had never regained his license.

48. Despite the fact that Johnson lost his medical license in 2001 under circumstances that reflect upon his competence and regard for public safety, subsequent advertisements and promotions for Osmosis products have violated the CFA by emphasizing Johnson’s status as a medical doctor in support of efficacy and performance claims (among other claims), without disclosing the loss of Johnson’s medical license.

Inadequacy of disclaimers

49. Various of Defendants’ promotional statements regarding the products that are the subject of this Petition have included some form of disclaimer, including, for example: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” However, neither this disclaimer nor any other disclaimer associated with Defendants’ products or promotions suffice to overcome the deceptive and otherwise unlawful aspects of Defendants’ conduct.

capabilities by its manufacturer.” (Quotes are from the order issued by the Board of Medical Examiners.)

²⁴ This was not Johnson’s first sanction by the Colorado Board of Medical Examiners. In 1998, the Board had issued a formal public reprimand to Johnson for prescribing Viagra “via the Internet and telephone for individuals with whom [Johnson] had not established a physician/patient relationship, had not physically examined, had not kept appropriate patient records,” and for whom the Board “could not determine . . . that the prescription being requested was warranted.” This, the Board concluded, constituted “unprofessional conduct.”

Disproportionate impact on older Iowans

50. Defendants' violations of the Consumer Fraud Act were such as to warrant a substantial civil penalty against each defendant for each violation of the CFA, pursuant to Iowa Code § 714.16 (7). In addition, for purposes of increasing such civil penalties in the manner set forth in the Older Iowans Law, Iowa Code § 714.16A: Many of such violations were rooted in conduct that was in willful disregard of the rights of older persons; Defendants knew or should have known that such conduct was directed to older persons; and older persons are substantially more vulnerable to such conduct on account of age and other factors. For these and other reasons, each qualifying civil penalty should be increased by \$5,000.00 (or by such lesser amount as the Court deems appropriate).

MISCELLANEOUS ALLEGATIONS

51. Upon information and belief, each defendant is liable for each alleged violation, including violations that may be described herein as directly related to the conduct of fewer than all defendants.

52. Neither all nor any part of the application for injunctive relief herein has been previously presented to and refused by any court or justice. Iowa R. Civ. P. 1.1504.

53. In an action by the State, no security shall be required of the State. Iowa R. Civ. P. 1.207.

COUNT I

CONSUMER FRAUD ACT VIOLATIONS

54. The Introduction and paragraphs 1 through 53 are incorporated herein by reference.

55. The Defendants' acts and practices violate the prohibition of Iowa Code § 714.16 (2)(a) against misleading, deceptive, and unfair acts and practices, and against omissions of material fact, and otherwise violate that subsection of the CFA.

56. Although it is not necessary to establish reliance, damages or intent to deceive to obtain injunctive relief or reimbursement under the Consumer Fraud Act, establishing these factors, particularly intent, is nevertheless relevant *inter alia* to the Court's determination of the scope of injunctive relief and the appropriate amount of civil penalties. Those acts and practices of Defendants in violation in subsection (2)(a) of the Consumer Fraud Act as alleged herein would in fact induce reliance on the part of the consumer victims, would in fact cause damage to consumers, and/or were in fact intentional.

COUNT II

OLDER IOWANS LAW VIOLATIONS

57. The Introduction and paragraphs 1 through 53 are incorporated herein by reference.

58. Defendant's violations of the Consumer Fraud Act were committed against older Iowans within the meaning of Iowa Code § 714.16A and give rise to the penalties set forth in that provision.

PRAYER

Plaintiff prays the Court grant the following relief:

A. Pursuant to Iowa Code § 714.16 (7), and upon further request by Plaintiff separately addressed to the Court, enter a preliminary injunction restraining Defendants, and each of them, and (as applicable) each such Defendant's directors, officers, principals, partners, employees, agents, servants, representatives, subsidiaries, affiliates, successors, assigns, merged or acquired predecessors, parents or controlling entities, and all other persons, corporations, and other entities acting in concert or participating with Defendants who have actual or constructive notice of the Court's injunction, from engaging in any of the deceptive, misleading, and unfair practices alleged in this Petition or otherwise violating the Iowa Consumer Fraud Act.

B. Pursuant to Iowa Code § 714.16 (7), after trial on the merits, make permanent the above-described injunctions, expanding their provisions as necessary by including, *inter alia*, such “fencing in” provisions as are reasonably necessary to ensure that Defendants and other enjoined persons and entities do not return to the unlawful practices alleged herein, or commit comparable violations of law.

C. Pursuant to Iowa Code § 714.16 (7), enter judgment against Defendants, jointly and severally, for amounts necessary to restore to Iowans all money acquired by means of acts or practices that violate the Consumer Fraud Act.

D. Pursuant to Iowa Code § 714.16 (7) enter judgment against Defendants, jointly and severally, for such additional funds as are necessary to ensure complete disgorgement of all ill-gotten gain traceable to the unlawful practices alleged herein.

E. Pursuant to Iowa Code § 714.16 (7), enter judgment against each Defendant for up to \$40,000.00 for each separate violation of the Consumer Fraud Act.

F. Pursuant to Iowa Code § 714.16A, the Older Iowans Law, enter judgment against each Defendant for a civil penalty of up to \$5,000.00 to be added to each civil penalty imposed under the Consumer Fraud Act.

G. Award Plaintiff interest as permitted by law.

H. Pursuant to Iowa Code § 714.16 (11), enter judgment, jointly and severally, against Defendants for attorney fees and state’s costs.

I. Retain jurisdiction as necessary to ensure full compliance with the pertinent provisions of the Consumer Fraud Act and the Older Iowans Law, and with the Court’s orders.

J. Assess court costs against Defendants.

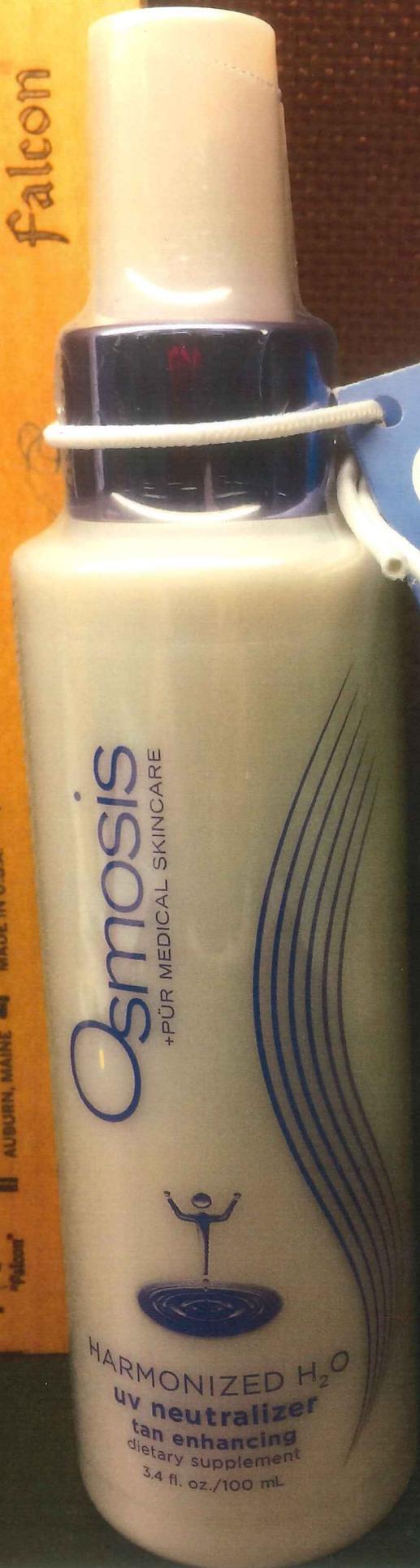
K. Grant such additional relief as the Court deems just and equitable.

Respectfully submitted,

Tom Miller
Attorney General of Iowa

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Osmosis
+PÜR MEDICAL SKINCARE



HARMONIZED H₂O
uv neutralizer
tan enhancing
dietary supplement
3.4 fl. oz./100 mL

Osmosis
+PÜR MEDICAL SKINCARE

Neutralizes UV Radiation
Allows for increased sun exposure
(30 x more than normal)





BEAUTIFUL SKIN STARTS WITHIN

- Includes frequencies that may improve sun tolerance
- May enhance tanning

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Supplement Facts

Serving Size: 5 Pumps

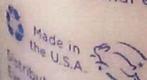
Amount Per Serving	% Daily Value
Water (Aqua) 2 mL	
	Daily Value not established

This formula contains the Osmosis Harmonized Water enhanced with proprietary frequencies in the form of solar waves.

Suggested Use: Take 5 pumps 1 hour prior to going outside (1.5 hours if there is any food in your stomach). If more than 175 lbs, take 7 pumps. Monitor sun exposure carefully. Take second dose if still outdoors 2 hours after first dose. For extended intense exposure outdoors or if taking sun-sensitizing medications, alternate protection after 30-40 minutes.

CAUTION: Do not exceed recommended dose. Pregnant or nursing mothers, children under 18, and individuals with a known medical condition should consult a physician before using this or any dietary supplement.

Keep out of reach of children. Do not use if safety seal is damaged or missing. Do not take right before heavy exercise for optimal effect, unless otherwise directed.



Made in the U.S.A.
Distributed by Osmosis, LLC
Broomfield, CO 80439
osmosiskincare.com



[Transcription of back of UV Neutralizer container]

BEAUTIFUL SKIN STARTS WITHIN™

- Includes frequencies that may improve sun tolerance
- May enhance tanning

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Supplement Facts

Serving Size: 5 Pumps

Amount Per Serving	% Daily Value
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Water (Aqua) 2 mL	†
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† Daily Value not established

This formula contains the Osmosis Harmonized Water, enhanced with proprietary frequencies in the form of scalar waves.

Suggested Use: Take 5 pumps 1 hour prior to going outside (1.5 hours if there is any food in your stomach). If more than 175 lbs, take 7 pumps. Monitor sun exposure carefully. Take second dose if still in sun 3 hours after first dose. For extended intense exercise outdoors or if taking sun-sensitizing medications, use alternate protection after 30-40 minutes.

CAUTION: Do not exceed recommended dose. Pregnant or nursing mothers, children under 18, and individuals with a known medical condition should consult a physician before using this or any dietary supplement.

Keep out of reach of children. Do not use if safety seal is damaged or missing. Do not take right before heavy exercise for optimal effect, unless otherwise directed.

Made in
the U. S. A.

Distributed by Osmosis, LLC
Evergreen, CO 80439
osmosisskincare.com
v01116

Initial Test

Apply traditional sun protection on most of the body. Leave an arm exposed.

Go in the sun as you normally would. If the arm does not burn, then you know it will work for you. If you are at risk (known sickness or sun-sensitizing medication like birth control pills), then increase your time in the sun systematically to determine how long UV Neutralizer lasts for you.

Osmosis

+PÜR MEDICAL SKINCARE

Neutralizes UV Radiation
Allows for increased sun exposure
(30 x more than normal)



Used at any age,
follow dosage, testing and
warning instructions

Dosing Instructions

Ideally you will take the first dose in the morning (before breakfast) an hour before you go into the sun.

Doses should be repeated every three hours if taken on an empty stomach. (Example: Take a dose at 8am to be in the sun at 9am. Take a second dose at 11am to be protected by noon when the 8am dose runs out. Take another dose at 2pm if you are staying in the sun until dinner).

0-80 lbs	81-160 lbs	161-240 lbs	241+ lbs
1 ml	2 ml	3 ml	4 ml

Warnings

- 1) Exercise with an elevated heart rate > 100 will reduce the time of efficacy to 30 minutes, 45 minutes with a double dose.
- 2) Sweating moderately to profusely will reduce protection in those areas.
- 3) Extended sun exposure with UV Index at 12 or higher requires secondary protection.
- 4) Most medications, illness, meat, dairy and alcohol may reduce your skin's tolerance to the sun.
- 5) Know your time limits of safe sun exposure for YOUR skin to get the best results with UV Neutralizer.

Evaluation of a Novel Form of Sun Protection

Paul Ver Hoeve, MD, FACS, Ben Johnson, MD

Abstract

This randomized clinical trial was designed to evaluate a product that utilizes a purported new technology, scalar waves, to provide sun protection. This examiner was skeptical about the claims of Harmonized Water and their "UV Neutralizer". Reportedly the product is water (there is no other active ingredient) that contains a form of radio-frequencies called scalar waves. Using a proprietary device, the company claims to be able to imprint hundreds of thousands of specific scalar waves onto water that, when ingested, vibrate above the skin to neutralize UVA and UVB. 24 patients were randomly selected to participate in this trial. Each of them ingested 3ml of UV Neutralizer and was then exposed to one hour of sun to one side of the body between noon and 1pm on June 28, 2014 in San Diego.

RESULTS: The participants were visually evaluated immediately after the sun exposure 24 hours later. 16 out of 24 patients did not burn during the testing. Notably, all of the patients who burned did not recall ever exposing their skin for such an extended period of time so we can assume many of them would burn regardless of the sun protection used. While this examiner cannot explain exactly how it worked, the testing provides evidence that this new form of sun protection is a viable alternative.

1. Introduction

Sun exposure has long been associated with sun damage to the skin along with an increased risk of developing skin cancer. To date, all forms of sun protection have been topical creams or sprays that must be reapplied frequently. Sunscreens contain chemicals that absorb UVB primarily but some newer chemicals have shown an ability to absorb UVA as well. In addition, zinc oxide and titanium dioxide can provide protection by reflecting the sun away from the skin. In all cases the products must be rubbed onto the surface of the skin. Controversy continues over whether or not the chemicals being used today are completely safe. Studies have shown that in many cases these chemical sunscreens increase the inflammation in

the skin [1,2,3,4,5,6,8,11]. Recently a study concluded that an SPF 50 chemical sunscreen did not protect against malignant melanoma [10]. While there is no doubt that using any sun protection is better than getting sunburned, there is more research needed on prevention of skin cancers including but not limited to basal cell carcinoma, squamous cell carcinoma and malignant melanoma.

Harmonized Water, specifically the UV Neutralizer formula, purports to be an effective alternative to traditional sunscreens. Through the use of a proprietary device, Harmonized Water is able to imprint a type of radio-frequency called scalar waves onto the molecules of water. The frequencies chosen for the test product were selected based on mathematical calculations for

UVA and UVB "cancellation effects". Upon ingestion of 2-3 ml of the water, the scalar waves reportedly work their way through the molecules of water in the body until they reach the water in the dermis. This process has been shown to take an hour on an empty stomach, 90 minutes if any food is present in the stomach. The scalar "cancellation" frequencies apparently then vibrate at the skin level for three more hours before diminishing. The product claims to prevent 97% of UVA/UVB from reaching the skin. While evidence for scalar waves exists, there has never been substantial evidence that these waves can be imprinted on water [7,9]. This examiner was skeptical of such claims, especially knowing that there does not appear to be a test to prove the deposition of scalar waves into the water. However, the potential benefits of such a feat warranted a clinical evaluation of UV Neutralizer.

Subjects and Methods

In this study, 24 patients were randomly selected as test subjects with no consideration for their natural skin tone. Their age range was from 18-60. The test subjects we screened to make sure that they: 1) could not be on medication in case that medication has a sun-sensitization effect, 2) did not have a medical condition that would influence their tolerance to sun exposure, 3) did not have any recent procedures on their skin that could negatively affect the results. The decision was made to not do a double-blind test for this application because of the ethical implications of knowingly causing a sunburn in many people. Therefore all 24 patients received 3ml of UV Neutralizer 90 minutes before their sun exposure. The test subjects

gathered at a location in San Diego, California in late June, 2014. They were exposed to continuous sun on one side of their body for one hour between noon and 1pm.

Evaluation of their skin was done by this examiner before, and immediately after their hour of sun. The following morning a second skin inspection of their skin was performed. The weather cooperated and the patients were tested on a clear, sunny day.

Results

16 out of 24 patients exposed one side of their body to summer sun after ingesting 3ml of UV Neutralizer 90 minutes before the study was initiated. All 24 patients were evaluated before, and immediately after the exposure as well as the following morning. There was no evidence of a sunburn on 16 patients, 5 had minor or partial sunburns and 3 had significant sunburns in the study. All of the patients who burned said they would not normally lay out in the sun for one hour. Many of them said they burn with the use of other sunscreens as well. This proves UV Neutralizer effectively limited the sun damage for a majority of the users that consumed it.

Comment

We cannot conclusively state that limited or no inflammation was created on the skin since biopsies were not part of the evaluation. However, visually there was no indication that any damage had occurred on any of the 16 patients without burns. Prior to testing, this examiner personally tried the UV Neutralizer for two hours in the sun to verify that the likelihood of a burn was low. This test

was also successful. Since that time it has been effective on every occasion.

While the science being reported is esoteric and theoretical in many respects, such definitive results warrant further evaluation of this product as well as the use of scalar waves in other applications. If, in fact, this product does protect at a level similar to SPF 30 products, then it has tremendous potential for widespread use.

Clearly more discussion needs to be performed on what percent of the population can tolerate sun exposure regardless of the sunscreen used. The incidence of skin cancer has risen dramatically and new research shows that the chemical sunscreens may not protect against cancer. The medical and dermatologic community discuss sun protection as it relates to UVA/UVB but not enough is said about the effect that medicines and illness have on the immune system's ability to heal sun exposure/damage. While we have identified several drugs that are sun sensitizing, there are many more that affect the skin but do not disclose that in

their literature. Sun sensitization is another subject worthy of debate. The fact that the capacity for the skin to heal has been compromised logically suggests that the overall healing ability of the immune system has been harmed by these medicines. We live in a country where more people take medicine than don't and that, combined with the skin cancer rise, should change the conversation to include assessments of people's overall health in relation to their sun exposure. The two cannot be separated.

While the results were not 100%, the authors believe this was due solely to the excessive amount of sun they received to their relatively virgin skin and their overall health. Those who sunburned said they have never stayed out in the sun for one hour on one side before. Several of the sunburned patients did not burn on the parts of the body which had been exposed to the sun recently. There is the basic premise that there are a select group of people who cannot undergo any long term (in this study, 1hr on one side) sun exposure. It is the author's opinion that a similar study using SPF 30 topical creams would produce a similar success rate.

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